10-12-00

A/Reissue

Please type a plus sign (+) inside this box → +

PTO/SB/50 (08-00)
Approved for use through 12/30/2000. OMB 0651-0033
U.S. Patent and Trademark Office; U.S DEPARTMENT OF COMMERCE

REISSUE PATENT APPLICATION TRANSMITTAL

Address to:

Assistant Commissioner for Patents
Box Reissue
Washington, DC 20231

Attorney Docket No.	11738.00001
First Named Inventor	Torgerson
Original Patent Number	5,820,589
Original Patent Issue Date (Month/Day/Year)	10/13/98
Express Mail Label No.	EM461378812US

APPLICATION FOR REISSUE OF: (Check applicable box) [XX] *Utility Patent* [ ] *Design Patent* [ ] *Plant Patent*

APPLICATION ELEMENTS (37 CFR 1.173)

1. [XX] Fee Transmittal Form *(PTO/ SB/ 56)* (*Submit an original, and a duplicate for fee processing*)
2. [ ] Applicant claims small entity status. See 37 CFR 1.27.
3. [XX] Specification and Claims in double column copy of patent format *(amended, if appropriate)*
4. [XX] Drawing(s) *(proposed amendments, if appropriate)*
5. [XX] Reissue Oath/Declaration (original or copy) *(37 C.F.R. § 1.175) (PTO/SB/51 or 52)*
6. Original U.S. Patent currently assigned?

   [XX] Yes [ ] No

   (If Yes, check applicable box(es))

   [XX] Written Consent of all Assignees *(PTO/SB/53)*

   [XX] 37 C.F.R. § 3.73(b) Statement (PTO/SB/96) [XX] Power of Attorney

ACCOMPANYING APPLICATION PARTS

7. [ ] Statement of status/support for all changes to the claims. See 37 CFR 1.173 (c).
8. [XX] Original U.S. Patent for surrender
   - [X] Ribboned Original Patent Grant
   - [ ] Statement of Loss (PTO/SB/55)
9. [ ] Foreign Priority Claim *(35 U.S.C. 119) (if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [ ] English Translation of Reissue Oath/Declaration *(if applicable)*
12. [ ] Preliminary Amendment
13. [XX] Return Receipt Postcard *(MPEP 503)* *(Should be specifically itemized)*
14. Other: .....

15. CORRESPONDENCE ADDRESS

[ ] *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* or [XX] *Correspondence address below*

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Signature	Scott Burow	Date	10/11/00

PTO/SB/56 (08-00)
Approved for use through 12/30/2000. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REISSUE APPLICATION FEE TRANSMITTAL FORM

Docket Number (Optional): 11738.00001

Claims as Filed - Part 1

Claims in Patent		Number Filed in Reissue Application	(3) Number Extra	Small Entity Rate	Small Entity Fee		Other than a Small Entity Rate	Other than a Small Entity Fee
(A) 8	Total Claims (37 CFR 1.16(j))	(B) 32	**** 12 =	x ____ =		or	x $18 =	$ 216.00
(C) 1	Independent claims (37 CFR 1.16(i))	(D) 5	* 4 =	x $____ =			x $80 =	$320.00
				Basic Fee (37 CFR 1.16(h))	$____			$710.00
				Total Filing Fee	$		OR	$ 1,246.00

Claims as Amended - Part 2

	(1) Claims Remaining After Amendment		(2) Highest Number Previously Paid For	(3) Extra Claims Present	Small Entity Rate	Small Entity Fee		Other than a Small Entity Rate	Other than a Small Entity Fee
Total Claims (37 CFR 1.16(j)	***	MINUS	**	* =	x $____ =			x $____ =	
Independent Claims (37 CFR 1.16(i))	***	MINUS	*****	=	x $____ =			x $____ =	
					Total Additional Fee	$		OR	$

* If the entry in (D) is less than the entry in (C), Write "0" in column 3.

** If the "Highest Number of Total Claims Previously Paid For" is less than 20, Write "20" in this space.

*** After any cancellation of claims.

**** If "A" is greater than 20, use (B - A); if "A" is 20 or less, use (B - 20).

***** "Highest Number of Independent Claims Previously Paid For" or Number of Independent Claims in Patent (C).

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ Please charge Deposit Account No. _____ in the amount of _____.
A duplicate copy of this sheet is enclosed.

XX ☒ The Commissioner is hereby authorized to charge any additional fees under 37 CFR 1.16 or 1.17 which may be required, or credit any overpayment to Deposit Account No. 01-2508.
A duplicate copy of this sheet is enclosed.

XX ☒ A check in the amount of $ 1,246.00 to cover the filing / additional fee is enclosed.

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10/11/00
Date

Scott Burow
Signature of Applicant, Attorney or Agent of Record

Scott A. Burow, Esq.
Typed or printed name

CERTIFICATE OF MAILING BY "EXPRESS MAIL"
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Deposited October 11, 2000

I hereby certify that the attached correspondence, identified below, is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" under 37 CFR § 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, BOX PATENT APPLICATION Washington, D.C. 20231.

By: _____
(person *actually* depositing)

In the Application of: TORGERSON

Serial No.:

Filing Date:

For: REISSUE APPLICATION FOR UNITED STATES PATENT 5,820,589

(X) Reissue Patent Application Transmittal in duplicate

(X) Reissue Application Fee Transmittal Form

(X) Executed - Combined Declaration, Power of Attorney and Written Assent of Assignee (4 sheets)

(X) Reissue Application for United States Patent 5,820,589 (14 pages/32claims, 5 independant) w/ Drawings (3 pages)

(X) Executed - Certificate of Ownership of Patent

(X) Executed - Offer to Surrender and Return Original Patent

(X) Original United States Patent 5,820,589

Attorney Docket No: 11738.02592

Reissue Application for United States Patent 5,820,589

Title: IMPLANTABLE NON-INVASIVE RATE-ADJUSTABLE PUMP

Inventors: Nathan A. Torgerson; Raymond F. McMullen
Assignee: Medtronic, Inc. (Minneapolis, MN)
Issued: October 13, 1998

FIELD OF THE INVENTION

The present invention relates generally to a method and apparatus for the delivery of fluid to a specific desired location within a patient's body; and, more particularly, relates to an implantable non-invasive, rate-adjustable pump for the delivery of pharmaceutical agents or other fluids to an implanted catheter or a desired location in a patient's body.

BACKGROUND OF THE INVENTION

Pharmaceutical agents and other fluids increasingly are being administered to patients through the use of pumps implanted within the patients' bodies. Generally, these drug infusion pumps may be classified as either fixed- or variable-rate pumps, depending upon the pump's flow rate characteristics.

Fixed rate implantable pumps typically are manufactured to deliver fluid at a preset flow rate. After manufacturing, the flow rate can not be changed. If a different rate is required by the patient, the original pump would need to be removed and a pump manufactured at the new flow rate would need to be implanted. An example of one such pump in use today is the Model 400™ manufactured by Infusaid.

Variable flow rate implantable pumps typically require that, prior to implantation, some mechanical means, e.g., a screwdriver be used by physicians to set the rate at which the fluids will

be delivered to the patient. After implantation, these pumps cannot be reset to a new flow rate without the pump being removed from the patient's body. An example of one such pump in use today is the IP35.1™ pump, available commercially from Anschutz, Kiel, Germany.

In an effort to avoid burdening patients with having to undergo an invasive surgical procedure to remove a fixed flow rate pump in order to manually adjust the flow characteristics of the device, drug infusion pumps with flow rates programmable after implantation were developed. These implantable pumps typically are powered by an internal battery. For example, the SynchroMed™ drug infusion pump, available commercially from Medtronic, Inc., Minneapolis, Minn., is an internally powered programmable pump having features which allow physicians to change fluid delivery parameters, such as flow rate, infusion period, ramp time, and bolus volume.

But while internally powered, variable flow rate programmable pumps represent a clear advance over prior fixed flow rate pumps, and they continue to enjoy widespread support and use by physicians worldwide, use of such pumps has drawbacks. For example, the device's useful life is restricted by the life of its internal power supply. An internal power supply eventually becomes depleted; thus, when the pump's internal battery runs out, the patient must undergo a surgical procedure to have the device removed and replaced. Currently, the average useful life of such a device is approximately 4-7 years. Further, in order to guard against the shortening of the device's useful life, such devices typically are not manufactured with additional power-consuming features within the device such as sensors or other medical diagnostic equipment which would prove useful to physicians in treating and monitoring their patients. Such equipment is excluded primarily because of a desire to avoid additional power drain to a device with an implanted power source having a fixed life. Finally, because these pumps are implanted into patients' bodies, it is desirable that they be as small as possible for patient comfort. However, there are limitations on how small

the internally powered variable flow rate programmable pump can be made because the internal power source takes up considerable space in the interior of the device.

SUMMARY OF THE INVENTION

As explained in more detail below, the implantable non-invasive rate adjustable pump of the present invention overcomes the above-noted and other shortcomings of prior implantable pumps. In accordance with the present invention, an implantable pump is programmed non-invasively by means of a programmer that communicates flow rate information by means of radio frequency telemetry or other methods of non-invasive telemetry. The programmer also supplies power to the implantable pump during programming. The implanted rate-adjustable pump that receives rate information and power by telemetry preferably does not include a battery or any other type of internal power supply, relying only on the energy obtained from the programmer through telemetry.

The implanted telemetry rate-adjustable pump is "powered up" during programming. To power up the device, the telemetry head of a programmer is placed over the patient's skin in the area in which the pump had been implanted. A telemetry signal then is received by an antenna in the pump, and associated circuitry in the pump is powered up. In other words, the programmer telemetry head sends a signal through the patient's skin in the area in which the pump is implanted. A generally flat coil of wire or other suitable receiving station inside the implanted unit proximate the patient's skin receives the signal, and a voltage is formed in the coil. This voltage, which in general remains as long as the programmer head and signal are in place, serves as a power source for the pump, thus eliminating the need for an internal battery.

Powering up a device using telemetry signals is not uncommon in certain medical applications unrelated to drug infusion pumps, e.g., implantable pulse generators and the like. With

those devices, as with drug infusion pumps, there is a desire to make the devices as small as possible for patient comfort. Thus, with certain model stimulators, like the Xtrel™ and Mattrix™ implantable stimulators, commercially available from Medtronic, Inc., Minneapolis, Minn., use of internal batteries has been avoided in favor of an external transmitting unit to power the devices. However, because stimulators require continuous power during operation, patients typically must carry an external transmitting unit with them at all times, usually on their belt.

In the implantable non-invasive rate-adjustable pump of the present invention application, however, the same need for continuous power does not exist. The primary power requirements comprise the energy needed to change the state of a valve or valve network in adjusting flow rates, and to operate certain other medical diagnostic components, e.g., sensors.

In accordance with the present invention, to change the flow rate of a drug infusion pump, the programmer sends, at the user's direction, flow rate programming commands or other signals using telemetry to the pump circuitry. In changing the flow rate, for example, signals sent to the pump circuitry would change the operating parameters of the electromechanical system that regulates the flow rate. Once the system is set in place, the system would not change its flow rate setting unless reprogrammed by the programmer. After all commands are sent and the desired programming and reprogramming of systems is complete, the programmer is taken away from the patient's skin. The pump then "powers down" and assumes a discharged state, keeping the newly programmed fluid flow rate settings.

In accordance with the present invention, then, in an adjustable rate implantable pump that is not limited by the life of a battery, options exist for flow rate adjustment methods and apparatus that would not be used in a pump whose life is limited by the life of the battery. For example, in a non-invasively powered adjustable rate implantable pump in which power is needed only to change

flow rates, and a pressurized reservoir maintains a fixed rate of flow through a restrictor network, the network preferably comprises a reservoir attached to a manifold with n bi-stable valves or a multi-stable valve with m states. These valves could be of various design, including, for example, shape-memory valves and bimetallic or laminated silicon/metal micromachined valves. The valves control the flow to n restrictors or regulators or a single restrictor or regulator when used with a multi-stable valve. With the bi-stable valve configuration, each restrictor has a different target flow rate, and the combination overall allows for 2^n flow rate options. With the multi-stable valves, the system has m flow rates. Both types of valves have no requirement for power except during flow rate changes. That power is provided by telemetry.

Thus, a non-invasively rate-adjustable pump in accordance with the present invention has an advantage over prior single rate restrictor pumps in that a new target rate can be selected non-invasively after the pump has been implanted by changing the state of a valve or valves. Further, the pump has advantages over prior implantable programmable pumps in that it can be used without an internal power supply that can run down and need to be replaced. Also, because a battery or other internal power supply is not required, the device can be built smaller in size. Finally, the power from the telemetry head may also be used to power electrical components in the pump, e.g., additional power-consuming components such as sensors for measuring flow rates; sensors for measuring drug volume in the reservoir; a needle detector for the septum; and any of the other additional useful components requiring energy in order to function.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic illustration of an exemplary implantable drug infusion pump in accordance with the present invention.

FIG. 2 is a schematic cut-away illustration of the exemplary implantable drug infusion pump of the present invention shown in FIG. 1, but with the top portion removed.

FIG. 3 is a schematic illustration in block diagram form of an implantable non-invasive rate-adjustable pump system in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

In accordance with the present invention, as shown in FIGS. 1-2, a drug infusion pump 10 includes a fluid reservoir 12 and a septum 14 which serves, for example, as an access port to the reservoir 12 during the filling of the reservoir with pharmaceutical agents or other fluids to be delivered to a specific desired location within a patient's body. The pump 10 further includes a telemetry antenna or receiver 16 preferably comprising a coil of wire within which a voltage may be induced when the receiver 16 is in the presence of a transmitted signal. Such a signal is created, for example, by an assembly including a programmer operatively coupled to a radio frequency head disposed proximate to a pump 10 implanted within the body of a patient near the skin.

The pump 10 further includes a system 20 that regulates the flow of fluid from the reservoir 12. Preferably, the system 20 comprises a valve network assembly adjustable to a plurality of flow rate settings, and includes a plurality of bi-stable valves that control the flow of fluid to a plurality of flow restrictors. The valves are similar to, but not restricted to those described by Wagner, et al. *See* Wagner, B. et al., "Bistable Microvalve with Pneumatically Coupled Membranes," IEEE 0-7803-2985-6/96, pp. 384-88, which is incorporated herein by reference. The restrictors are similar to, but not limited to capillary tube technology used in the commercially available Infusaid and Anschutz fixed rate pumps. Alternatively, micro-machined etching technology can also be used to manufacture the restrictor.

In addition, the pump 10 preferably includes control circuitry 18 for changing the state of one or more of the valves of the system 20 in response to a received telemetry signal. The control circuitry 18 preferably includes elements required to communicate with the transmitter, transform the signal from the transmitter to energy required to change valve states according to the telemetry received via the transmitter, and verify valve states and overall pump performance.

FIG. 3 shows a schematic illustration of an implantable non-invasive rate-adjustable pump system in accordance with the present invention. As shown therein, the pump 10 preferably also includes a plurality of sensors and other components 26 (*a, b, c, . . .*) for use by physicians as diagnostic tools as part of the overall medical treatment plan for the patient. For example, as shown in FIG. 3, sensor 26(*a*) comprises a tool for measuring drug volume in the reservoir 12; and component 26(*b*) comprises a sensor for measuring flow rates. The components 26 (*a, b, c, . . .*) generally are power-consuming components which, preferably receive their energy from non-invasive programming signals or sense commands originating in a programmer or some other similar device.

Although the preferred embodiment of this invention has been described hereinabove in some detail, it should be appreciated that a variety of embodiments will be readily available to persons utilizing the invention for a specific end use. The description of the apparatus and method of this invention is not intended to be limiting on this invention, but is merely illustrative of the preferred embodiment of this invention. Other apparatus and methods which incorporate modifications or changes to that which has been described herein are equally included within this application. Additional objects, features and advantages of the present invention will become apparent by referring to the above description of the invention in connection with the accompanying drawings.

What is claimed is:

1. An implantable medical pump, comprising:

a fluid reservoir;

a passive regulator assembly adjustable to a plurality of flow rate settings for regulating the flow of fluid from the fluid reservoir;

electromechanical control means for changing the passive regulator assembly from a first flow rate setting to a second flow rate setting when the electromechanical control means receives an induced voltage and in response to control signals; and

means for receiving radio frequency signals operative to maintain the induced voltage in the electromechanical control means in response to received radio frequency signals.

2. The implantable medical pump of claim 1, wherein the means for receiving radio frequency signals is further operative to provide control signals to the electromechanical control means in response to received radio frequency signals.

3. The implantable medical pump of claim 2, wherein the regulator assembly for regulating the flow of fluid from the fluid reservoir comprises a valve.

4. The implantable medical pump of claim 2, wherein the regulator assembly for regulating the flow of fluid from the fluid reservoir comprises a valve and a flow restrictor, and wherein the valve is operatively coupled to the flow restrictor.

5. The implantable medical pump of claim 2, wherein the regulator assembly for regulating the flow of fluid from the fluid reservoir comprises a plurality of valves and a flow restrictor network which are operatively coupled.

6. The implantable medical pump of claim 2, wherein the radio frequency signals are received from a programmer.

7. The implantable medical pump of claim 2, further comprising means for sensing, in response to a received radio frequency sense command, the amount of fluid in the fluid reservoir.

8. The implantable medical pump of claim 7, wherein the sense command is received from a programmer.

9. An implantable medical pump, comprising:

a fluid reservoir;

a valve for controlling the flow of fluid from the fluid reservoir;

a plurality of flow restrictors operatively coupled to the valve for providing a plurality of flow rates of the fluid from the fluid reservoir; and

a control for changing the flow rate setting of the valve in response to a received control signal.

10. The implantable medical pump of claim 9 further comprising a receiver within which a voltage is induced when the receiver is in the presence of the control signal.

11. The implantable medical pump of claim 10 wherein the control signal is a radio frequency signal.

12. The implantable medical pump of claim 11 wherein the radio frequency signal is received from a programmer.

13. The implantable medical pump of claim 9 further comprising a first sensor for measuring the flow rate of the fluid.

14. The implantable medical pump of claim 13 further comprising a second sensor for measuring the volume of fluid in the fluid reservoir.

15. An implantable medical pump, comprising:

a fluid reservoir;

a multi-stable valve having multiple states for providing a plurality of flow rates of fluid from the fluid reservoir;

a flow restrictor operatively coupled to the multi-stable valve for regulating the flow rate of fluid from the fluid reservoir;

a control for changing the flow rate setting of the multi-stable valve in response to a received control signal.

16. The implantable medical pump of claim 15 further comprising a receiver within which a voltage is induced when the receiver is in the presence of the control signal.

17. The implantable medical pump of claim 16 wherein the control signal is a radio frequency signal.

18. The implantable medical pump of claim 17 wherein the radio frequency signal is received from a programmer.

19. The implantable medical pump of claim 15 further comprising a first sensor for measuring the flow rate of the fluid.

20. The implantable medical pump of claim 19 further comprising a second sensor for measuring the volume of fluid in the fluid reservoir.

21. An implantable medical pump, comprising:

a fluid reservoir;

a plurality of valves for controlling the flow of fluid from the fluid reservoir;

a flow restrictor network operatively coupled to the plurality of valves for providing a plurality of flow rates of the fluid from the fluid reservoir; and

a control for changing the flow rate setting of the plurality of valves in response to a received control signal.

22. The implantable medical pump of claim 21 further comprising a receiver within which a voltage is induced when the receiver is in the presence of the control signal.

23. The implantable medical pump of claim 22 wherein the control signal is a radio frequency signal.

24. The implantable medical pump of claim 23 wherein the radio frequency signal is received from a programmer.

25. The implantable medical pump of claim 21 further comprising a first sensor for measuring the flow rate of the fluid.

26. The implantable medical pump of claim 25 further comprising a second sensor for measuring the volume of fluid in the fluid reservoir.

27. An implantable medical pump, comprising:

a fluid reservoir;

a plurality of valves for controlling the flow of fluid from the fluid reservoir;

a flow restrictor for regulating the flow rate of fluid from the fluid reservoir; and

a control for changing the flow rate setting of the plurality of valves in response to a received control signal.

28. The implantable medical pump of claim 27 further comprising a receiver within which a voltage is induced when the receiver is in the presence of the control signal.

29. The implantable medical pump of claim 28 wherein the control signal is a radio frequency signal.

30. The implantable medical pump of claim 29 wherein the radio frequency signal is received from a programmer.

31. The implantable medical pump of claim 27 further comprising a first sensor for measuring the flow rate of the fluid.

32. The implantable medical pump of claim 31 further comprising a second sensor for measuring the volume of fluid in the fluid reservoir.

ABSTRACT

In accordance with the present invention, an implantable pump is programmed non-invasively by means of a programmer that communicates flow rate information by means of radio frequency telemetry or other methods of non-invasive telemetry. The programmer also supplies power to the implantable pump during programming. The implanted rate-adjustable pump that receives rate information and power by telemetry preferably does not include a battery or any other type of internal power supply, relying only on the energy obtained from the programmer through telemetry.

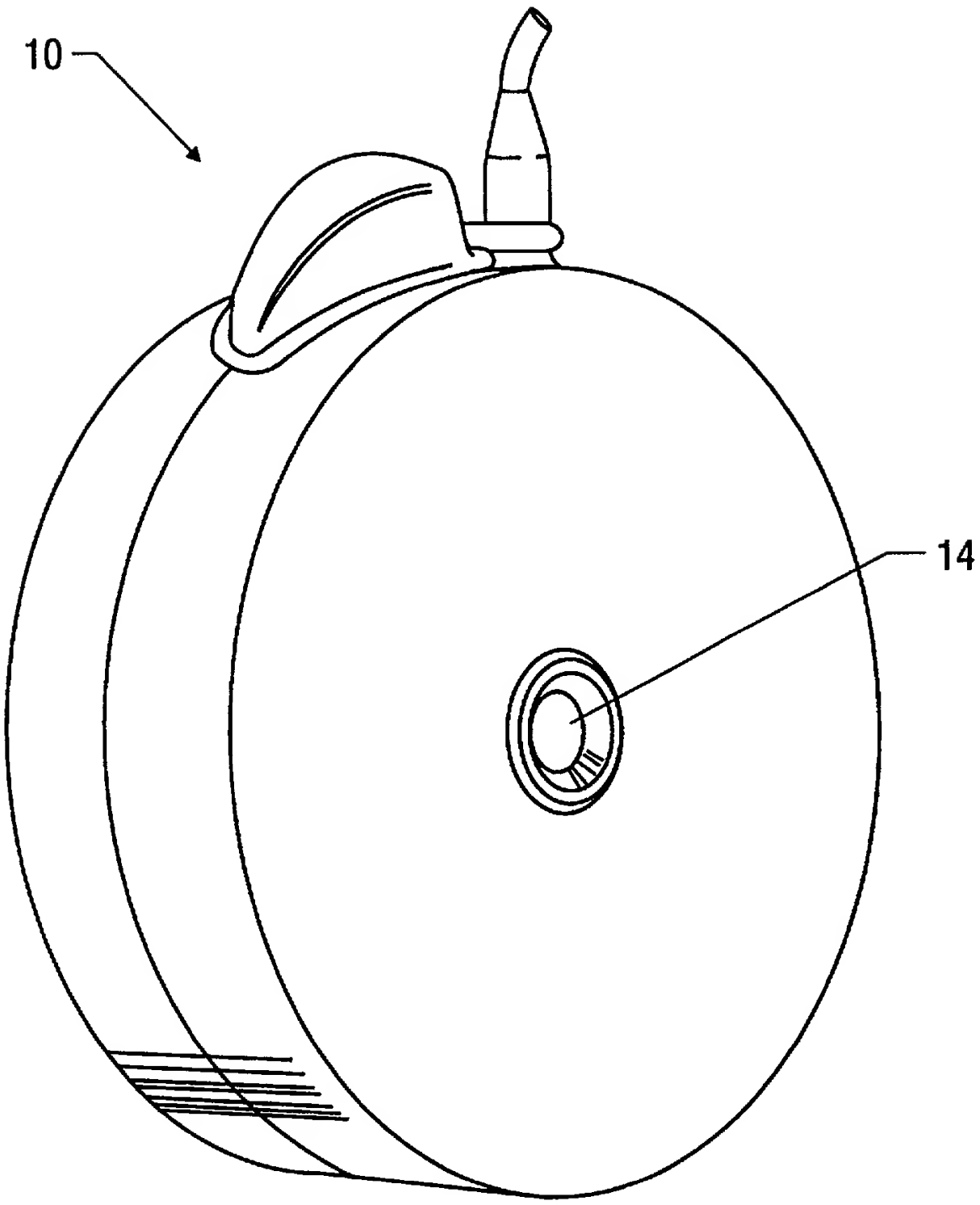

FIG. 1

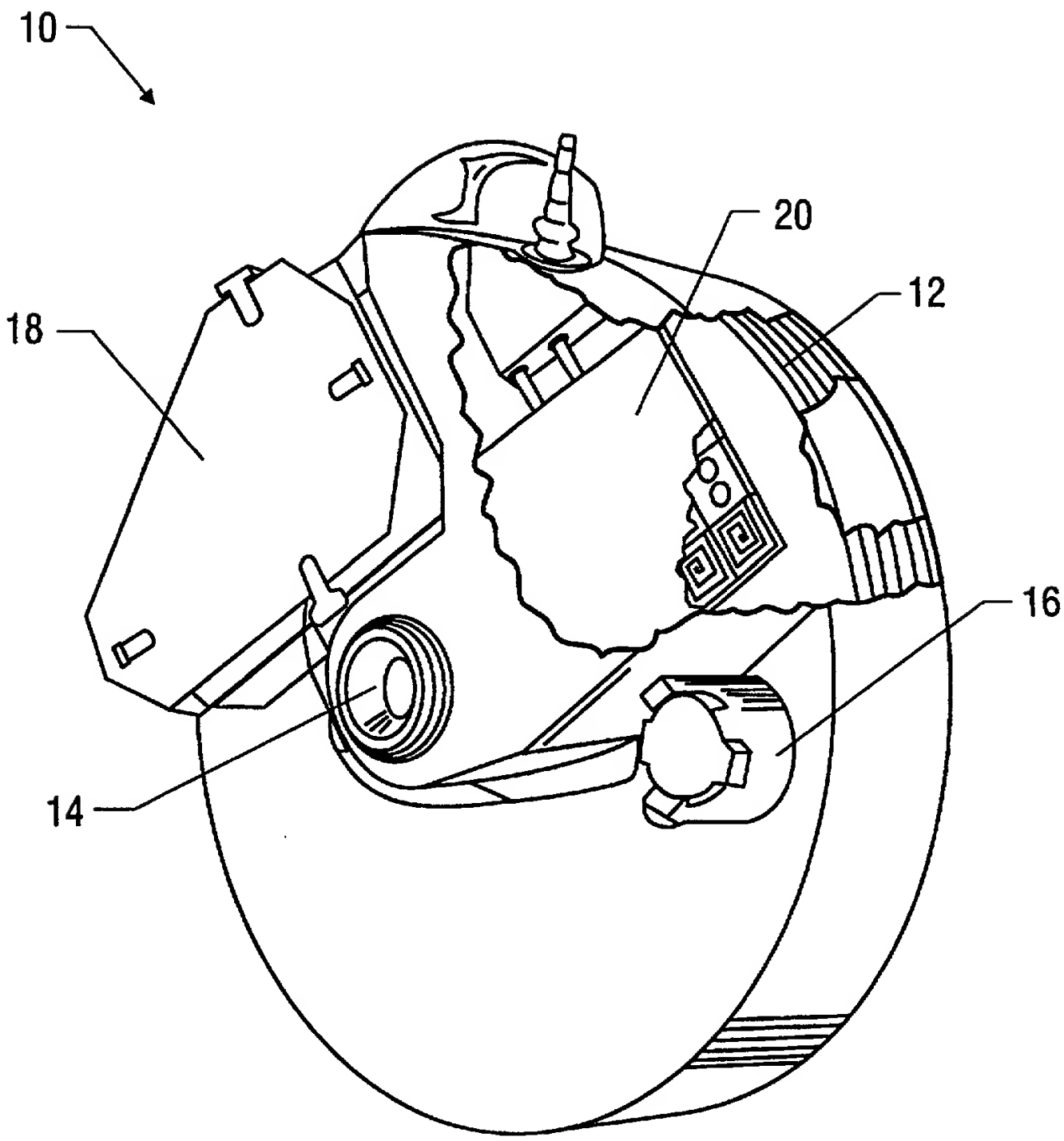

FIG. 2

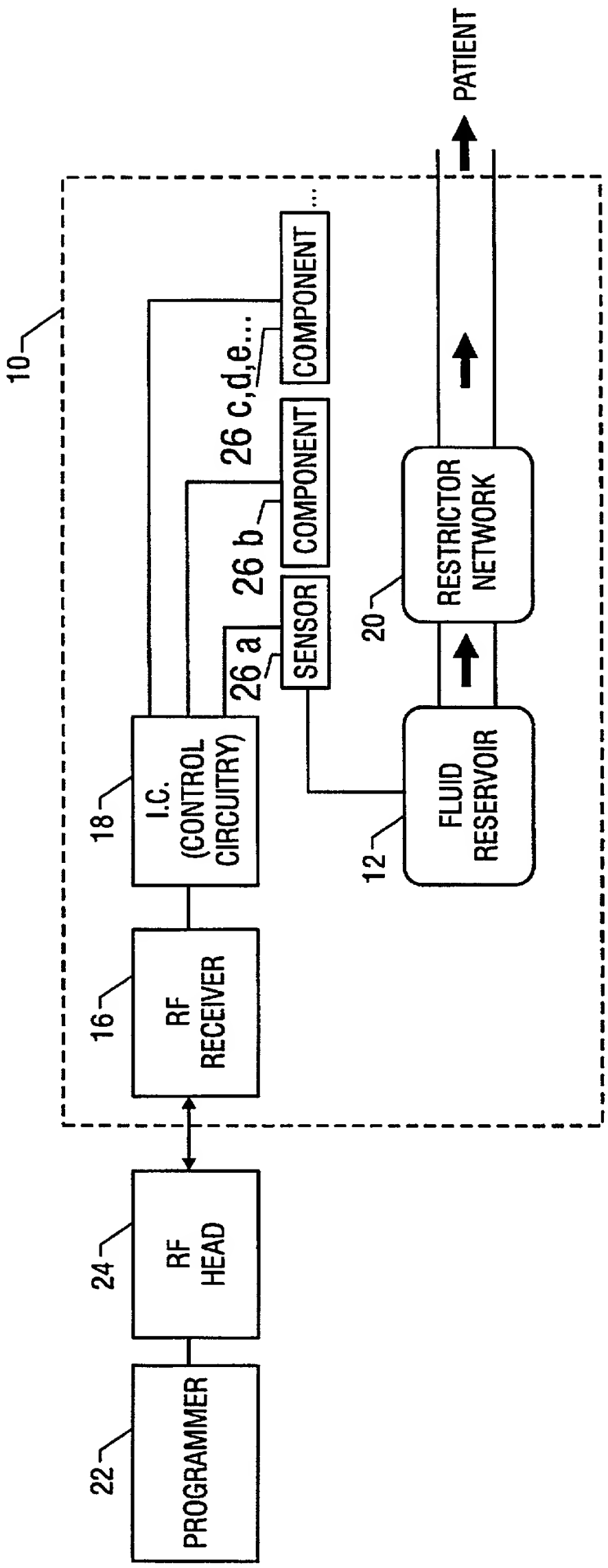
PATIENT
10
I.C. (CONTROL CIRCUITRY)
18
26 a
SENSOR
26 b
COMPONENT
26 c,d,e...
COMPONENT
20
RESTRICTOR NETWORK
12
FLUID RESERVOIR
16
RF RECEIVER
24
RF HEAD
22
PROGRAMMER

FIG. 3

Attorney Docket No. 11738.00001

COMBINED DECLARATION, POWER OF ATTORNEY, and WRITTEN ASSENT OF ASSIGNEE

As the below named inventor, I hereby declare that:

This declaration is of the following type:

[ ] original
[ ] divisional
[ ] continuation
[ ] continuation-in-part
[x] reissue

INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

"IMPLANTABLE NON-INVASIVE RATE-ADJUSTABLE PUMP"

The specification of which:

[X] is attached hereto.

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information I know to be material to patentability in accordance with 37 C.F.R. §1.56.

PRIORITY CLAIM (35 U.S.C. §120)

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Application Number	Filing Date	Status — patented, pending, abandoned
641,363	April 30, 1998	U.S. Patent No. 5,820,589

REISSUE DECLARATION OF APPLICANT

I believe the original patent to be wholly or partly inoperative or invalid by reason of claiming less than I had a right to claim in the patent.

Specifically, I claimed subject matter that was less than that described in the original patent but not described in the art that existed prior to the effective filing date of the original patent. In particular, described in the original patent is the use of a plurality of valves or a network of restrictors (or a combination of both) to regulate the fluid flow from the fluid reservoir. This subject matter, not claimed in the original patent, is considered patentable over the prior art. Thus, the scope of the claims of the original patent is unduly narrow through errors in recognizing the true scope of the invention in view of the prior art. The reissue application overcomes these defects in the original patent.

All errors which are being corrected in the reissue application up to the time of filing of the reissue application arose without any deceptive intention on my part.

POWER OF ATTORNEY

I hereby appoint the following attorneys and agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:
as my Attorneys.

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Joseph P. Krause	Reg. No. 32578	Christopher P. Moreno	Reg. No. 38566
John P. Iwanicki	Reg. No. 34628		

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Inventor's signature: Nathan A. Torgerson Date: Oct 10, 2000

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WRITTEN ASSENT OF ASSIGNEE

Medtronic, Inc. is the Assignee of the entire right, title and interest in and to U.S. Patent No. 5,820,589, and hereby gives its written assent to this reissue application.

Medtronic, Inc.

By:

Title: V.P. Chief Patent Counsel

Date: Oct 10, 2000

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Date: Oct 10, 2000